IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AUXILIUM PHARMACEUTICALS, INC. and FCB I, LLC, Plaintiffs, v. UPSHER-SMITH LABORATORIES, INC., Defendant.	C. A. No. 13-148-SLR REDACTED PUBLIC VERSION

DEFENDANT UPSHER-SMITH LABORATORIES, INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF THE PATENTS-IN-SUIT

OF COUNSEL:

Ronald J. Schutz
Jake M. Holdreith
Lars P. Taavola
Jaime R. Kurtz
Robins, Kaplan, Miller & Ciresi L.L.P.
2800 LaSalle Plaza
800 LaSalle Avenue
Minneapolis, MN 55402

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Anne Shea Gaza (#4395)
gaza@rlf.com
Travis S. Hunter (#5350)
hunter@rlf.com
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
302-651-7700

Attorneys for Defendant Upsher-Smith Laboratories, Inc.

Dated: April 5, 2013

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Statutes

I. INTRODUCTION

This is a simple case. As a matter of law, Upsher-Smith Laboratories, Inc. ("USL") does not infringe any of the patents-in-suit. The patents-in-suit all recite a specific drug formulation that requires specific ingredients. As Plaintiffs have acknowledged, one of those specific ingredients is not found in USL's proposed formulation. Therefore, as a matter of law, USL's proposed formulation cannot literally infringe any of the patents-in-suit.

Plaintiffs are also barred from asserting that USL's formulation infringes the patents under the doctrine of equivalents. The prosecution history provides two independent bases that bar Plaintiffs from resorting to the doctrine of equivalents. First, the patent owner gave up any and all equivalents to its special ingredient as a matter of law during prosecution, when the patentee amended the claims to require the specific ingredients for reasons of patentability. All claims in the family were amended to require the same or closely related ingredients. Second, the patentee made arguments during prosecution of all of the patents-in-suit that clearly and unmistakably prevent the patentee from arguing that USL's ingredients are an equivalent. In these arguments, the patentee expressly agreed that a large category of specific ingredients are outside the scope of the claims. USL's proposed formulation uses ingredients that the patentee distinguished from what it claimed as its invention.

In addition, the doctrine in *W.M. Wrigley Jr. Co. v. Cadbury Adams USA LLC* bars the application of the doctrine of equivalents in this case, even without considering the estoppel issues. 683 F.3d 1356 (Fed. Cir. 2012). Narrow claims reciting specific members of a class of chemical compounds cannot be enlarged by the doctrine of equivalents to reach other chemical compounds.

USL moves for summary judgment of non-infringement of all of the patents-in-suit on the basis that Plaintiffs admit there is no literal infringement and that they are barred from invoking

the doctrine of equivalents as a matter of law. The patents-in-suit are U.S. Patent Nos. 7,320,968 ("the '968 patent"); 7,608,605 ("the '605 patent"); 7,608,606 ("the '606 patent"); 7,608,607 ("the '607 patent"); 7,608,608 ("the '608 patent"); 7,608,609 ("the '609 patent"); 7,608,610 ("the '610 patent"); 7,935,690 ("the '690 patent"); 8,063,029 ("the '029 patent"); and 8,178,518 ("the '518 patent") (collectively "the patents-in-suit").

II. NATURE AND STAGE OF THE PROCEEDINGS

This case raises patent infringement issues that have been before this Court for over four years. Plaintiffs filed the instant action on January 28, 2013. D.I. 1. USL promptly filed its Answer on January 30, 2013. D.I. 7. The subject of this action is USL's 505(b)(2) application filed with the FDA for a testosterone gel product. In the Complaint, Plaintiffs acknowledged the related case *Auxilium Pharma. Inc. v. Upsher-Smith Labs. Inc.*, 08-908-SLR (D. Del., filed December 4, 2008) ("the related action"). The subject of the related action is USL's ANDA filed with the FDA for a testosterone gel product. While there are differences between the USL applications pending at the FDA, the issues are identical for the purposes of evaluating patent infringement. [redacted]. All claims of the patents-in-suit recite a specific formulation for a testosterone gel with specific ingredients. While only one patent is at issue in the related action, the additional patents-in-suit in the instant action derive from that patent by a claim of priority, and have the identical specification.

Discovery in the related action was substantially complete and opening expert reports were due at the time the related action was closed administratively. Since the initiation of the instant action, USL has produced a copy of its 505(b)(2) application and has completed its document production to Plaintiffs. Discovery in the related action permitted Plaintiffs access to USL's

formulation since 2009, and Plaintiffs also had access to product samples for testing. Therefore, Plaintiffs have known for some time that USL's formulation does not infringe the patents-in-suit.

III. SUMMARY OF ARGUMENT

1. USL's proposed formulation does not literally infringe any claim of the patents-in-suit. Each claim of the patents-in-suit requires a specific formulation of testosterone gel with specific ingredients. As Plaintiffs have admitted, USL's proposed formulation does not include one of those special ingredients and therefore cannot literally infringe.

2. Plaintiffs are estopped as a matter of law from asserting the doctrine of equivalents based upon amendments made during prosecution. During prosecution of the patents-in-suit, the patentee made narrowing amendments for the purpose of patentability that limited the scope of patents to ingredients specifically recited in the claims. Therefore, Plaintiffs are barred from invoking the doctrine of equivalents to assert that the different ingredients used in USL's proposed formulation infringe the patents-in-suit.

3. Plaintiffs are also estopped as matter of law based upon arguments made throughout the prosecution of the patents-in-suit. During prosecution, the patentee faced prior art that discloses the ingredients used in USL's formulation. The patentee made clear and unmistakable arguments that the large category of ingredients listed in the prior art reference were outside the scope of the patent claims. USL's formulation uses ingredients specifically disclosed in the prior art and disclaimed by the patentee.

4. The doctrine of equivalents is also foreclosed under *Wrigley v. Cadbury* because narrow patent claims reciting specific ingredients within a chemical family, like the patents-in-

suit, may not be enlarged to cover structurally different chemical compounds by the doctrine of equivalents. 683 F.3d 1356.

IV. STATEMENT OF FACTS

A. The Undisputed Facts Show that USL's Proposed Formulation Falls Outside the Scope of the Patents-In-Suit.

The facts relevant to this motion are straightforward and not in dispute. The patents-in-suit all claim priority to the same application (which issued as U.S. Patent No. 7,320,968 ("the parent patent")) and claim methods for treating hypogonadism using a specific formulation of a testosterone gel or a pharmaceutical composition containing the specific formulation. D.I. 1, Ex. A-J. Each of the patents-in-suit has the same, identical specification. *Id.*

Gel formulations for transdermally delivering testosterone or other hormones were already well known at the time the parent patent application was originally filed. D.I. 1, Ex. A, col. 3, ll. 34-59. [1] The sole named inventor on all the patents-in-suit, Robert J. Gyurik, purportedly invented a testosterone gel comprising a specific group of improved "penetration enhancers." A "penetration enhancer" is an ingredient which increases the rate of passage of the active ingredient, e.g., testosterone, through the skin membrane. D.I. 1, Ex. A, col. 3, ll. 46-51. Specifically, the patents' specification describes only the use of so-called cyclic "Hsieh enhancers" D.I. 1, Ex. A, Abstract.

As the patentee recognized during prosecution of the patents, hundreds (perhaps thousands), of penetration enhancers for testosterone gels were already well known in the art and

[1] All of the patents-in-suit are continuations of the parent '968 patent and share a common specification. Therefore, for ease of reference, citations are to the '968 patent specification which is substantially identical to the specification of all of the patents-in-suit.

disclosed in, *inter alia*, U.S. Patent No. 6,503,894 ("the Dudley patent"). Ex. 1, pp. 24-25.[2] Therefore, to get patents, the patentee was required to draft patent claims that were limited to a testosterone gel with the specific penetration enhancers for which the patentee provided comparative testing. In particular, each claim of the '605 patent, '606 patent, '607 patent, '609 patent and the '518 patent requires the specific penetration enhancer oxycylcohexadecane-2-one ("Oxa-2-one"). D.I. 1 at Exs. B-D, F, J. Each claim of the'608 patent, '610 patent, '690 patent and the '029 patent requires the specific penetration enhancer Oxa-2-one or one of a selected and closely-related group of four of the so-called macrocyclic "Hsieh enhancer" compounds – 3-methylcyclopentadecanone, 9-cycloheptadecen-1-one, cyclohexadecanone and cyclopentadecanone. D.I. 1 at Exs. E, G, H, I. These selected Hsieh enhancer compounds are all macrocyclic compounds containing at least 12 carbon atoms in a ring structure. D.I. 1, Ex. A, col. 7, ll. 8-18, Ex. 3.

USL's proposed formulation does not contain any of these cyclic Hsieh enhancer compounds. In fact, [redacted]

B. The Scope of the Patents-in-Suit Was Limited During Prosecution by Amendment of the Claims in Response to an Examiner's Rejection.

The patentee filed narrowing amendments during prosecution of the parent patent. These amendments were clearly necessary to gain issuance of the patents-in-suit. In making these amendments, the patentee explicitly limited the claims of the patents-in-suit to a narrow class of specific macrocyclic compounds, while disclaiming an extensive list of compounds including the exact compounds used in USL's formulation. The patentee cannot recapture claim scope that was

[2] "Ex. __" refers to the Declaration of Lars P. Taavola and the exhibits attached thereto, filed contemporaneously herewith.

explicitly disavowed during prosecution and, thus, as a matter of law USL cannot be found to infringe the patents-in-suit.

1. In Prosecuting the Parent Patent, the Patentee Limited the Scope of the Patented Invention to a Specific Enhancer ("Oxa-2-one") by Filing a Narrowing Amendment.

In the parent application, the patentee initially attempted to include a broad class of all macrocyclic penetration enhancers—called Hsieh enhancers—in the scope of the claims. Ex. 4, p. 4. These Hsieh enhancers were known in the prior art for delivering a drug through the skin, and were explicitly defined as cyclic compounds with at least 12 carbons in a specific chemical structure. D.I. 1, Ex. A, col. 7, ll. 8-18.

During the following exchange, the patentee originally tried to claim all Hsieh enhancers as its invention, but was forced by the patent examiner to narrow the claims to a single, very specific enhancer called oxacylohexadecan-2-one or "Oxa-2-one" for short.[3] During prosecution, claim 40 and claim 62 were among the pending claims and read as follows:

> 40. A method for delivering at least one androgen to a patient in need thereof comprising the step of administering to said patient a composition comprising: (A) an androgen; (B) a Hsieh enhancer; and (C) a thickening agent.
>
> 62. A method according to Claim 40 wherein said enhancer is oxacyclohexadecan-2-one.
>
> Ex. 1, pp. 4, 5 (emphasis added).

The Examiner conducted an interview with the applicant's attorney on June 12, 2007, during which the Examiner concluded that not all Hsieh enhancers could be claimed by the patentee as its invention. In the interview, the Examiner explicitly directed the patentee to amend the

[3] Oxacylohexadecan-2-one is also sometimes called "pentadecalactone" for supposed ease of reference, an alternative that only a chemist could consider to be a simple name. All three names refer to the identical chemical: Oxacylohexadecan-2-one, pentadecalatone, and Oxa-2-one.

pending claims to include the specific enhancer recited in claim 62, namely Oxa-2-one. Ex. 4, p. 3.

After the interview, the patentee filed narrowing amendments to explicitly recite Oxa-2-one in the independent method claims. The patentee stated:

> Reference is made to the Examiner's "Interview Summary," mailed June 19, 2007, which indicates the allowability of the claims (that is, the elected method claims) if the claims are amended to define the composition which is referred to in the claims as containing oxacyclohexadecan-2-one (hereafter OXA-2-one), which is the enhancer referred to in dependent claim 62, and testosterone. By virtue of the present claim amendments, all pending claims now define the composition as containing testosterone and OXA-2-one. In addition, it is submitted respectfully that all of the claims are appropriate in form and content and, therefore, are allowable.
>
> Ex. 5, p. 9.

The patentee did not amend the claims further and the Examiner issued a Notice of Allowability on September 5th, 2007. Ex. 7. In the Notice, the Examiner cancelled most of the pending claims, but, importantly, proposed new independent claim 118, which included the

specific ingredient Oxa-2-one at the concentration which appears in issued claim 1 of the patent. *Id.* at pp. 2-3. Mr. Barron soon thereafter authorized claim 118, with the included specific ingredient Oxa-2-one. The patent issued in January 2008 with the explicit, narrowed limitation to Oxa-2-one in all claims. (D.I. 1 at Ex. A).

2. The Patents-in-Suit Rely on the Parent Patent's Narrowing Amendment and Are Likewise Limited in Scope.

This case concerns ten patents in the same patent family: the original patent discussed above and nine "children" patents deriving from continuation applications. The allowability of the continuation applications therefore rests on the same original discussion with the patent examiner, and each was required to include, in all claims, Oxa-2-one or very closely related macrocyclic enhancers.

Specifically, all of the patents-in-suit claim priority to the original '968 patent, and are subject to terminal disclaimers. The originally filed independent claims – none of which were allowed – were not limited to the small group of Oxa-2-one and the closely related macrocyclic enhancers. During prosecution of each of the children patents, the patentee surrendered the broader class of Hsieh enhancers and filed claims adding Oxa-2-one or the four closely-related compounds as an explicit limitation.

During prosecution of the '518 patent, to overcome a rejection, the patentee was required to amend the claims to specifically recite Oxa-2-one so as to include the narrow structural limitations of the composition claimed in the '968 patent. Ex. 8, p. 6.[4] At the outset of prosecution of the '605 patent, '606 patent, '607 patent, '608 patent, '609 patent, and '610 patent (collectively, "600 series patents"), the patentee filed Petitions to Make Special. Exs. 9-14. With

[4] In his rejection, the Examiner, the same Examiner that reviewed the prosecution of the '968 patent, explained his rationale for granting the '968 patent. According to the Examiner, the '968 patent was granted based on the combination of the purported surprising results and the eight specific components (i.e. ingredients) in the amounts recited in the claims. Ex. 8, pp. 5-6.

these petitions, the patentee agreed that the claims were directed to a single invention and identified written description support in the parent patent specification. *Id.* As with the parent patent, all the claims of the'605 patent, '606 patent, '607 patent, and '609 patent are limited to a formula that includes Oxa-2-one. D.I. 1, Exs. B-D. Similarly, the '608 patent and '610 patent require that the formulation contain Oxa-2-one or a closely related macrocyclic/Hsieh enhancer selected from a specific group of four closely related macrocyclic compounds. D.I. 1, Exs. E, G.

During prosecution of the two remaining patents-in-suit (the '690 patent and the '029 patent), the patentee attempted to broaden the claims to cover Hsieh enhancers generally—rather than the subset of five specific Hsieh enhancers claimed in the '608 and '610 patents. Exs. 15-16. This was the same thing the original patent examiner had refused to allow the patentee to claim during the original prosecution of the parent patent. During prosecution of the '029 patent, the Examiner likewise rejected the renewed effort to seek the broadened claim limitation. This time, the Examiner concluded that the patentee had not shown that he actually invented anything more than a formula with one of the five specific macrocyclic enhancers, stating that "the specification does not provide a showing that the various compound cores and ring sizes of Hsieh enhancers can produce and maintain the testosterone blood levels....." Ex. 17, p. 5.

In response, the patentee amended the claim to list five specific Hsieh enhancers—all of which are macrocyclic Hsieh enhancers (i.e. compounds with 12 carbons in the ring)—and no other macrocyclic compounds. Ex. 18, p. 2; Ex. 19, p. 2. In the Reasons for Allowance, the Examiner specifically stated that the recitation of these specific enhancers in the amended claims was a reason for patentability because the amendments limited the scope of the claims to be supported by the patentee's previous showing of nonobviousness for the five specific tested Hsieh enhancers. With respect to the '029 patent, the Examiner stated "[t]he claims have been

amended to be *limited in scope* to be commensurate with the previous presentation for nonobviousness of the five specific tested Hsieh enhancers." Ex. 20, p. 2. The Examiner made a similar statement in the Reasons for Allowance of the '690 patent. The Examiner stated "the amended independent claim recites the method of treatment of hypogonadism with a composition comprising several components including the claimed Hsieh enhancers not present in Dudley." Ex. 21, p. 2.

C. The Patentee Clearly and Unmistakably Surrendered the Class of Enhancers Used in USL's Formulation by Statements Made During Prosecution of the Patents.

Not only did the patentee agree to narrow its patent claims to a formula with macrocyclic enhancers, but the patentee also made arguments during prosecution that his invention is different from formulations that use other, known penetration enhancers. In other words, in order to get a patent, the patentee said that formulations made with conventional enhancers are not within the scope of the claims. The patentee made these statements in arguments to overcome rejections based on the Dudley patent cited by the Examiner, and its teaching that a large number of known penetration enhancers could be used to make a testosterone gel.

1. During Prosecution of the Parent Patent, the Patentee Argued for Patentability by Disavowing Other Enhancers to Overcome Cited Prior Art.

The Examiner rejected the claims of the parent application under 35 U.S.C. § 103 as being unpatentable over the Dudley patent which, at a minimum, disclosed hundreds of enhancers for use in a testosterone gel. Ex. 1, pp. 24-25. To overcome this rejection, the patentee argued that the patented formula required the use of specific Hsieh enhancers, unlike the Dudley patent that "describes a whole host of various types of compounds that can be used as the enhancer, including prior art enhancers . . . Among all of the hundreds of enhancers (perhaps

thousands) disclosed by Dudley et al., there is no reference whatsoever to a Hsieh enhancer. . . ." *Id.*

The patentee also submitted a declaration of Dr. Kenneth Walters in an attempt to overcome the obviousness rejection based on the Dudley patent. Ex. 22. This declaration was submitted to show that the alleged invention is different from testosterone gels made with conventional enhancers of the Dudley patent, by providing comparative test results of a composition disclosed in the Dudley patent and a composition of the claimed invention. *Id.* at p. 7. Dr. Walters concluded that the formulation of the claimed invention, using the specific Hsieh enhancers, was surprisingly effective when compared to the composition disclosed in the Dudley patent. *Id.* The Examiner was persuaded by the patentee's arguments made in the declarations, and stated that "[t]he declarations go to the benefits of the *specific combination* of the instant formulation for use in hypogonadism such as the specific incorporation of testosterone with…the specific enhancer oxacyclohexadecan-2-one." Ex. 7, pp. 3-4 (emphasis added).

2. During Prosecution of the Child Patents, the Patentee Relied on Arguments Made During Prosecution of the Parent Patent and Argued for Patentability by Disavowing Other Enhancers.

In another set of exchanges, the patentee made a separate and additional set of statements that make it clear that the claimed invention is specific to a narrow group of macrocyclic enhancers. During prosecution of the children applications, the Examiner found in each case that the claims were not patentably distinct from those that issued in the parent patent, and issued a non-statutory double patenting rejection. Exs. 23-30. To overcome this rejection, instead of arguing against the rejection, the patentee filed a terminal disclaimer and disclaimed the term of all of the child patents to that of the '968 patent. Ex. 31. In other words, the patentee did not

argue that the child patents rested on any broader alleged invention than the specific formula claimed in the parent patent with its specific Oxa-2-one ingredient.

In addition, in prosecuting the child patents, the patentee relied heavily on statements that were made during prosecution of the parent application, as all of the patents-in-suit faced an obvious rejection based partly on the Dudley patent, just like the original parent patent. Exs. 32-40. To overcome these rejections, the patentee pointed to statements made during the prosecution of the parent application, including the Walters Declaration, and claimed unexpected results based upon the use of Oxa-2-one. *Id.*

D. USL's Proposed Formulation Does Not Contain the Claimed Penetration Enhancers, But Rather Contains Three Ingredients That Were Among the "Enhancers" The Patentee Clearly and Unmistakably Distinguished from Its Claimed Enhancers.

None of the ingredients in USL's formulation are: (a) Hsieh enhancers; (b) macrocyclic enhancers; or (c) the specifically claimed Oxa-2-one and its closely related cyclic compounds. Ex. 3. Rather, USL's proposed formulation contains ingredients specifically listed in the cited Dudley patent, the leading prior art reference, which disclosed a testosterone gel and a whole host of penetration enhancers. As noted above, in each instance the patentee amended the claims to overcome the rejection in view of Dudley, and distinguished its invention by arguing that "[a]mong all of the hundreds of enhancers (perhaps thousands) disclosed by Dudley et al., there is no reference whatsoever to a Hsieh enhancer...." Ex. 1, pp. 24-25. The patentee thus disclaimed the Dudley enhancers from the scope of the claims based on the amendments and the arguments made during prosecution.

Specifically, in describing the penetration enhancer useful in the disclosed formulations, the prior art Dudley patent teaches that:

> Non-limiting examples of penetration enhancers include C8-C22 fatty acids such as isostearic acid, octanoic acid, and oleic acid; C8-C22 fatty alcohols such as **oleyl alcohol** and lauryl alcohol; lower alkyl esters of C8-C22 fatty acids such as ethyl oleate, isopropyl myristate, butyl stearate, and **methyl laurate**; di(lower) alkyl esters of C6-C8 diacids such as **diisopropyl adipate**; monoglycerides of C8-C22 fatty acids such as glyceryl monolaurate; tetrahydrofurfuryl alcohol polyethylene glycol ether; polyethylene glycol, propylene glycol . . ..

Ex. 41, col. 12, ll. 45-54 (emphasis added).

USL's proposed formulation contains oleyl alcohol, methyl laurate and diisopropyl adipate – all disclosed in the Dudley patent and dismissed by the patentee on the basis that they are not Hsieh enhancers, let alone the specific five macrocyclic compounds claimed in the asserted patents. Ex. 2. [redacted] Thus, a competitor would reasonably believe, based on the objective evidence in the prosecution history, that the patentee disclaimed the Dudley enhancers from the claim scope based on the amendments and the arguments made during prosecution.

V. STANDARD OF LAW

A court should grant summary judgment when no reasonable jury could return a verdict for the nonmoving party. *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). Summary judgment is particularly appropriate in complex patent infringement actions because it is a useful tool to secure a just and speedy determination of the action and to simplify and pare down the issues. *See, e.g., KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007). The non-moving party has the burden to present evidence that a genuine dispute exists that compels trial after the moving party has shown that there is no genuine issue of material fact. *Celotex Corp. v. Catrett,* 477 U.S. 317, 323-24 (1986).

It is well settled that to literally infringe a patent claim, the accused product or process must "contain each limitation of the claim exactly" and that "any deviation from the claim precludes" a finding of infringement. *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1454 (Fed. Cir. 1998); *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1330 (Fed. Cir. 2001). When every limitation is not literally present, a patentee's only resort is to argue infringement under the doctrine of equivalents. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997).

Prosecution history estoppel serves as a limit on the doctrine of equivalents and presents a question of law. *Glaxo Wellcome, Inc. v. Impax Labs., Inc.*, 356 F.3d 1348, 1351 (Fed. Cir. 2004). If the Court determines, upon reviewing the relevant prosecution history, that estoppel applies, infringement under the doctrine of equivalents is precluded as a matter of law, and summary judgment of non-infringement is appropriate. *See id.* "Prosecution history estoppel can occur during prosecution in one of two ways, either (1) by making a narrowing amendment to the claim ('amendment-based estoppel') or (2) by surrendering claim scope through argument to the patent examiner ('argument-based estoppel')." *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1375 (Fed. Cir. 2007) (citing *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*,460 F.3d 1349, 1363 (Fed. Cir. 2006)); *see also Bayer AG v. Elan Pharm Research Corp.*, 212 F.3d 1241, 1251 (Fed. Cir. 2000).

A narrowing amendment made to satisfy any requirement of the Patent Act may give rise to an amendment-based estoppel. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (*Festo VIII*). Prosecution history applies if the narrowing amendment was made for a substantial reason relating to patentability. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366-67 (Fed. Cir. 2003) (en banc) ("*Festo X*"). The scope of the

subject matter surrendered by the narrowing amendment is evaluated with the presumption of total surrender. *Id.* at 1367. A patentee cannot rebut this presumption if the particular equivalent is known in the pertinent prior art at the time of amendment. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 493 F.3d 1368, 1378 (Fed. Cir. 2007) ("*Festo XIII*"); *Festo X*, 344 F.3d at 1369-70.

Similarly, in argument-based estoppel, unmistakable assertions made by the applicant to the PTO in support of patentability, whether or not required to secure allowance of the claim, may operate to preclude the patentee altogether from asserting equivalency. *Bayer*, 212 F.3d at 1252. In determining whether there has been a clear and unmistakable surrender of subject matter, the Court must examine the prosecution history as a whole. *Id.* Courts are to examine the prosecution history from an objective standpoint. The proper inquiry is "whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter."[5] *Id.* (citations omitted). If so, the patentee is completely estopped from asserting the doctrine of equivalents for the surrendered subject matter. *See id.* This inquiry is for the court as a matter of law. *Id.* at 1251.

Importantly, the Federal Circuit has recognized that "prosecution disclaimer may arise from disavowals made during the prosecution of ancestor patent applications." *MBO Labs., Inc. v. Becton, Dickenson & Co.*, 602 F.3d 1306, 1318 (Fed. Cir. 2010) (citations omitted); *see also, Augustine Med. Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1301 (Fed. Cir. 1999) (finding that prosecution history estoppel bars extending the patent claims because "during prosecution of the '102, '320, and '371 patents, Augustine Medical amended the claims to expressly include a 'self-

[5] Testimony about what a reasonable competitor would conclude from the prosecution history cannot create a genuine issue of material fact so as to bar summary judgment. "Such testimony is only a tool" that a Judge uses at his or her discretion to aid in the legal determination of prosecution history estoppel. *Bayer*, 212 F.3d at 1254.

erecting' limitation and made clear representations of the scope of that limitation to overcome the prior art."); *Trading Tech. Int'l, Inc. v. BCG Partners, Inc.*, 852 F. Supp. 2d 1027, 1047-48 (N.D. Ill. 2012) (finding that the patentee surrendered scope during prosecution of a parent application). In addition, "any argument-based estoppel affecting a limitation in one claim extends to all claims in which that limitation appears." *AstraZeneca UK Ltd. v. Dr. Reddy's Laboratories, Ltd.*, No. 08-3237, 2010 WL 4721384, at *6 (D.N.J. Nov. 15, 2010) (citing *Eagle Comtronics, Inc. v. Arrow Commc'n Labs., Inc.*, 305 F.3d 1303, 1316 (Fed. Cir. 2002)).

VI. ARGUMENT

This case presents no genuine issue of material fact, and USL is entitled to summary judgment. USL's proposed formulation does not infringe the patents-in-suit, either literally or under the doctrine of equivalents. In a crowded art, the patentee received narrow patent claims using a well-known drug and a very specific penetration enhancer, Oxa-2-one and four closely related cyclic compounds. USL's proposed formulation does not contain any of the specific penetration enhancers recited in the claims and cannot, as a matter of law, literally infringe the patents. [6]

Furthermore, Plaintiffs are estopped from asserting infringement under the doctrine of equivalents based on both amendment-based and argument-based prosecution history estoppel. During prosecution of the parent patent, the patentee was forced to amend the claims to specifically recite Oxa-2-one to gain patentability. The child applications, which led to the other nine patents-in-suit, all recite Oxa-2-one or four closely related macrocyclic compounds as an ingredient in the enhancer limitation, and thus Plaintiffs are foreclosed from asserting equivalents with respect to the recited limitations.

[6] In the related action against USL regarding USL's ANDA, Auxilium admitted that USL does not literally infringe any claims of United States Patent 7,320,968 ("the '968 patent"), the patent that issued from the parent application of the remaining patents-in-suit. Ex. 43, pp. 5-6.

Similarly, during prosecution of the parent patent, to traverse a rejection in light of the Dudley patent, the patentee disclaimed the ingredients described in the Dudley patent. The patentee clearly surrendered any claim scope on formulations containing the penetration enhancers disclosed in the Dudley patent, such as USL's proposed formulation. Plaintiffs are estopped in this litigation from capturing what the patentee told the patent office and the public was surrendered during prosecution: namely, any formulation that does not include the specifically claimed enhancers, Oxa-2-one and its four closely related macrocyclic compounds.

Plaintiffs are also foreclosed from asserting the doctrine of equivalents under *Wrigley v. Cadbury*. In *Wrigley*, the Federal Circuit held that narrow patent claims reciting a specific chemical ingredient may not be enlarged to encompass structurally different compounds through the doctrine of equivalents. In this case, as in *Wrigley*, the patents-in-suit narrowly recite the specific ingredient Oxa-2-one and closely related cyclic compounds, and not the broader category of ingredients described in the Dudley patent. Plaintiffs cannot enlarge their patents to sweep in this broader category of chemicals and reach USL's formulation.

Summary judgment of no infringement as a matter of law is warranted and disposes of all claims asserted by the Plaintiffs in this action.

A. USL's Proposed Formulation Does Not Contain the Recited Enhancers, and Therefore, USL Cannot Literally Infringe Any of the Patents-In-Suit.

USL's proposed formulation does not literally infringe the patents-in-suit because it does not contain the claimed Oxa-2-one or its closely related macrocyclic compounds recited in each claim of the patents-at-issue. [redacted] Since USL's proposed formulation does not "contain each limitation of the claim exactly" a finding of literal infringement is precluded. *Litton Sys.*, 140 F.3d at 1454; *Telemac*, 247 F.3d at 1330.

B. The Court Should Grant USL's Motion Because the Undisputed Facts Show that Plaintiffs are Estopped, as a Matter of Law, From Asserting that the Accused Formulation Infringes the Patents-In-Suit under the Doctrine of Equivalents.

Courts have not hesitated to grant summary judgment when estoppel precludes application of the doctrine of equivalents as a matter of law. [redacted] certainly not equivalent to the five claimed macrocyclic Hsieh enhancer, but the court need not even reach that issue on summary judgment because, in this case, Plaintiffs are estopped from asserting infringement of USL's proposed formulation under the doctrine of equivalents. Three separate legal barriers bar Plaintiffs from asserting infringement in this case. First, narrowing amendments were made during prosecution for the purposes of patentability which limited the patents to the recited penetration enhancers, Oxa-2-one and its closely related cyclic compounds. Second, arguments were made during prosecution that show a clear and unmistakable surrender of the subject matter Plaintiffs are now trying to claim in litigation, namely, the Dudley penetration enhancers—the exact enhancers in USL's proposed formulation. Third, the patentee's narrow claiming of selected members of a class of chemical compounds bars Plaintiffs in this case from capturing by the doctrine of equivalents compounds wholly outside the class under *Wrigley v. Cadbury*.

1. Narrowing Amendments Made During Prosecution Estop Plaintiffs from Asserting Equivalence of USL's Proposed Formulation.

Plaintiffs must live with the narrowing amendments reciting specific penetration enhancers, and cannot recapture, through the doctrine of equivalents, that which was surrendered during prosecution. *See Festo XIII*, 493 F.3d at 1377 (citing *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1579 (Fed. Cir. 1995)). During prosecution of the parent patent, and for reasons squarely related to patentability, the patentee was forced to amend the original method claims to specifically recite the special ingredient Oxa-2-one. There can be no dispute that the

Oxa-2-one limitation was added by amendment to gain patentability in the parent application: the Examiner explicitly demanded such amendment, and the patentee explicitly stated that the amendment was made to gain patentability. Ex. 4, p. 3; Ex. 5, p. 10. [redacted] The patentee had to make a similar amendment to gain allowability of the '518 patent. Ex. 8, p. 6.

Such amendment-based prosecution history estoppel also prevents Plaintiffs from expanding the scope of the remaining child patents. The patents-in-suit are not patentably distinct from the claims of the parent patent, which was narrowly limited to compositions comprising Oxa-2-one. *See Augustine Med. Inc.*, 181 F.3d at 1301 (finding that prosecution history estoppel bars extending the patent claims because "during prosecution of the '102, '320, and '371 patents, Augustine Medical amended the claims to expressly include a 'self-erecting' limitation and made clear representations of the scope of that limitation to overcome the prior art.") Thus, amendment based estoppel applies to the enhancer limitation (Oxa-2-one or closely related macrocyclic compounds) of all patents-in-suit. Therefore, the patentee is not entitled to any equivalents to the enhancer limitations.

The patentee's subsequent attempts to broaden their patent monopoly by expanding the claims of the '690 patent and the '029 patent to cover Hsieh enhancers generally were likewise rebuffed by the Examiner. To gain allowance, the patentee was required to amend the claims to recite five specific macrocyclic Hsieh enhancers that were specifically tested in comparative testing and were alleged to have unexpected results. Ex. 20, p. 2; Ex. 21, p. 2. Because of these amendments, the claims recite only the five specific Hsieh enhancers, and amendment-based estoppel applies.

Plaintiffs cannot rebut the presumption of the amendment-based estoppel. Only limited bases for rebutting the presumptive estoppel are permitted, and none are available in this case. Plaintiffs cannot show that any alleged equivalent in USL's formulation could not reasonably have been described at the time the amendment was made, that the alleged equivalent was tangential to the purpose of the amendment, or that the equivalent was not foreseeable (and thus not claimable) at the time of the amendment. *Festo XIII,* 493 F.3d at 1352. The Examiner was clear that, with respect to each patent-in-suit, the recitation of the specific enhancer was central to patentability. *Festo X*, 344 F.3d at 1369 ("an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim.").

Moreover, USL's proposed formulation uses ingredients that were explicitly listed as enhancers in the leading prior art reference, and thus the ingredients were clearly foreseeable at the time of the amendment. *See id.* ("if the alleged equivalent were known in the prior art in the field of the invention, it certainly should have been foreseeable at the time of the amendment.") Thus, Plaintiffs cannot rebut the presumption of amendment-based prosecution history estoppel.

2. Plaintiffs are Estopped from Asserting that the Ingredients in USL's Proposed Formulation are Equivalent to the Patented Enhancers based on Arguments Made during Prosecution.

Alternatively, Plaintiffs are estopped from claiming that USL's proposed formulation is equivalent based on arguments made during prosecution. During prosecution of the parent patent and the child patents, the Examiner rejected claims based on the Dudley patent and the enhancers disclosed in it. In distinguishing Dudley, the patentee clearly and unmistakably surrendered any formulation that does not include Oxa-2-one or the other listed macrocyclic Hsieh enhancers. Thus, a competitor, like USL, would reasonably believe that the patentee had surrendered any claim to the Dudley enhancers.

During prosecution, the patentee repeatedly argued that enhancers recited in Dudley were well-known in the prior art and not within the scope of the claims being sought. For instance, to overcome the rejection over Dudley, the patentee distinguished its claimed "Hsieh enhancer" by arguing: "[a]mong all of the hundreds of enhancers (perhaps thousands) disclosed by Dudley et al., there is no reference whatsoever to a Hsieh enhancer. . . ." Ex. 1, pp. 24-25 (emphasis added). The "hundreds of enhancers" disclosed in the Dudley patent include the ingredients used in USL's proposed formulation. Ex. 2, Ex. 41, col. 12, ll. 35-54. As shown above, each is explicitly recited in the Dudley passage that discusses enhancers.

Further, during prosecution of the parent patent and the children patents, the patentee filed the declaration of Dr. Kenneth Walters, who also characterized the Dudley enhancers as well-known in the prior art. In his declaration, Dr. Walters argued that the singularity and uniqueness of the enhancer used in its formulation, Oxa-2-one, when compared to the enhancers disclosed in the Dudley patent produced unexpected results, and thus the claims were not obvious. *See AstraZeneca*, 2010 WL 4721384, at *8 (The Court concluded that the Federal Circuit has "found clear and unmistakable surrender when the patentee asserted the singularity or uniqueness of the claimed invention in arguing for its patentability.") When the patentee attempted to broaden its claims to Hsieh enhancers generally during the prosecution of the '690 patent, the '029 patent, and the '518 patent, the Examiner rejected the claims outright and only allowed the claims once the patentee had demonstrated, through comparative testing, that the four additional specifically-listed Hsieh enhancers also produced "surprising" results.

In addition to claiming surprising results over the Dudley compositions, the patentee disparaged the Dudley compositions for numerous shortcomings:

> Examples of topical androgen gels include those described in U.S. Pat. Nos. 5,968,919 to Samour et al. and 6,503,894 to Dudley et al....Disadvantages

> associated with the aforementioned topical androgen gels include, for example, the inconsistency of the gels and the lack of emollient properties; their use leads to drying of the skin and skin irritation. In addition, the gel of the '894 patent is capable of delivering a relatively low amount of testosterone through the skin and the gel of the '919 patent contains an enhancer which tends to irritate the skin.
>
> D.I. 1 at Ex. A., col. 3, ll. 51-67.

Because the patentee clearly disclaimed the Dudley enhancers to obtain the patents-in-suit, Plaintiffs cannot now expand the scope of the patent claims to reach subject matter that was clearly disclosed in the leading prior art reference.

C. Even if Plaintiffs had not Disclaimed and Estopped Themselves, the Narrow Claiming of Five Specific Cyclic Hsieh Enhancers Forecloses the Doctrine of Equivalents under *Wrigley v. Cadbury.*

The doctrine of equivalents is foreclosed in this case not just by estoppel in the prosecution history, but by the doctrine of *Wrigley v. Cadbury. Wrigley* holds that narrowly and explicitly reciting specific members of a chemical family as an ingredient in a patent claim based on its supposedly surprising effectiveness forecloses the use of the doctrine of equivalents to reach other, different ingredients. *Wrigley,* 683 F.3d at 1366. In the present case, the specification discloses only Hsieh enhancers as part of the invention, and the patent claims are narrowly drafted to recite the specific macrocyclic compounds Oxa-2-one and four closely related macrocyclic compounds based on their supposedly surprising effectiveness. As dictated by *Wrigley*, Plaintiffs are foreclosed from arguing that the patent can be expanded by resort to the doctrine of equivalents to include compounds in USL's formulation that are neither cyclic nor Hsieh enhancers.

The facts in this case are remarkably similar to *Wrigley*. In *Wrigley*, Cadbury held a patent claiming chewing gum compositions containing the cooling ingredients menthol and "N-substituted-p-menthane carboxamides." *Id.* at 1358. As shown in Cadbury's patent, this

particular class of chemicals recited in the patent claims is cyclic (i.e. ring-structured), just like the macrocyclic enhancers recited in all claims of the patents-at-issue in this case. Wrigley sold gums containing menthol and an ingredient known as WS-23, which is not cyclic and is not an "N-substituted-p-menthane carboxamide." *Id.* at 1359. Wrigley was sued for infringement by Cadbury, and moved for summary judgment of non-infringement.

In granting summary judgment of non-infringement for the accused infringer and against the patentee, the district court found that the narrow and explicit claim limitation to N-substituted-p-menthane carboxamides foreclosed the use of the doctrine of equivalents to reach other and different ingredients such as the accused WS-23. *Id.*

The Federal Circuit affirmed the district court's grant of summary judgment. On appeal, the parties agreed that there was no literal infringement because WS-23 (the alleged equivalent) is not one of the claimed N-substituted-p-menthane carboxamide compounds. The sole infringement issue facing the Federal Circuit was infringement under the doctrine of equivalents. *Id.* at 1365.

The Federal Circuit determined that Cadbury could not expand its claims to cover WS-23 using the doctrine of equivalents. *Id.* at 1366. The Federal Circuit reasoned that Cadbury only claimed to invent the use of a very specific subset of cyclic chemical ingredients in a chewing-gum composition, based on testing that the specifically recited ingredients led to unexpected results. Therefore, the Federal Circuit determined that the patentee could not assert equivalence to extend its patent claims to chewing gum that uses structurally different ingredients. The Cadbury patent was based on unexpected results using the specific combination of the cyclic N-substituted-p-menthane carboxamides and menthol. *Id.* at 1365-66. The patent's specification pointed to a subset of N-substituted-p-menthane carboxamides – not all carboxamides – that are

similar in structure to menthol. *Id.* at 1366. The Federal Circuit noted that the alleged equivalent WS-23, which is not ring-structured, is not structurally similar to menthol while N-substituted-p-methane carboxamides are similar to methol. *Id.* The Court further noted that the Cadbury claims were narrow, not even claiming all N-substituted-p-menthane carboxamides, but only a subset of those compounds. *Id.* Therefore, the Court held that Cadbury could not expand its patent coverage to capture the broader category of chemicals through the doctrine of equivalents. *Id.*

The facts in this case parallel *Wrigley* and require the same result. The patentee only claimed to invent the use of a very specific subset of macrocyclic chemical ingredients (five specific Hsieh enhancers) to improve testosterone gel compositions. The patentee wrote a narrow disclosure and pursued narrow claims, which were allowed by the Examiner based on comparative testing that demonstrated allegedly unexpected results for the five specifically recited enhancers. Like Cadbury, the patentee here got his patent by combining known ingredients – testosterone and specific Hsieh enhancers.

Like the specification of the Cadbury patent, the specification of the patents-in-suit describes an invention that incorporates only specific species of a chemical additive: in the case of the patents-in-suit, cyclic penetration enhancers called Hsieh enhancers. Like Wrigley's WS-23, the accused ingredients in USL's formulation are not cyclic and therefore are not structurally similar to what the patentee described and recited in his claims. Like the Cadbury claims, the patentee's claims are narrow – the patentee was not even allowed claims to all Hsieh enhancers, but only to a subset of those compounds. Furthermore, like the Cadbury inventors, the inventor in this case knew of the accused ingredients when he applied for a patent, but did not claim them. The ingredients listed in Dudley and used in USL's formulation were known penetration enhancers, and clearly known to the inventor at the time that his patent specification was drafted

and filed with the patent office. The patentee had to distinguish the Dudley patent, and its disclosure of enhancer ingredients, repeatedly during prosecution. *Id.* at 1366.

The result here must be the same as in *Wrigley*. Plaintiffs are estopped altogether from asserting the doctrine of equivalents against any and all formulations that do not include the explicitly and narrowly claimed five special ingredients.

Accordingly, even if the Court were to consider only the specification and claims of the patents-in-suit, the doctrine of equivalents is entirely foreclosed. The patents speak for themselves in this case – any reasonable competitor, based on an objective reading of the specification and claims, would reasonably believe that the patentee invented no more than was disclosed and claimed in his patents, and that the exclusionary scope of the patents is no broader than the claims.

Here, in addition to the narrow specification and claims, the Court must consider the explicit estoppels that go far beyond the facts that led to summary judgment in *Wrigley*. The undisputed facts and controlling law require granting USL's Motion for Summary Judgment of Non-Infringement of the Patents-in-Suit.

VII. CONCLUSION

For the reasons set forth above, Auxilium and FCB I are estopped as a matter of law from asserting that USL infringes U.S. Patent Nos. 7,320,968; 7,608,605; 7,608,606; 7,608,607; 7,608,608; 7,608,609; 7,608,610; 7,935,690; 8,063,029; and 8,178,518 literally or under the doctrine of equivalents. This case presents no genuine issue of material fact. Therefore, the Court should grant Upsher-Smith's Motion for Summary Judgment of Non-Infringement of the Patents-in-Suit and enter judgment in favor of USL on the Plaintiff's complaint.

/s/ Travis S. Hunter

Frederick L. Cottrell, III (#2555)
cottrell@rlf.com
Anne Shea Gaza (#4395)
gaza@rlf.com
Travis S. Hunter (#5350)
hunter@rlf.com
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
302-651-7700

ATTORNEYS FOR DEFENDANT UPSHER-SMITH LABORATORIES, INC.

OF COUNSEL:

Ronald J. Schutz
Jake M. Holdreith
Lars P. Taavola
Jamie R. Kurtz
Robins, Kaplan, Miller & Ciresi L.L.P.
2800 LaSalle Plaza
800 LaSalle Avenue
Minneapolis, MN 55402

Dated: April 5, 2013

CERTIFICATE OF SERVICE

I hereby certify that on April 5, 2013, I caused to be served by electronic mail and hand delivery copies of the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

Steven J. Balick
Lauren E. Maguire
Andrew C. Mayo
Ashby & Geddes
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
sbalick@ashby-geddes.com
lmaguire@ashby-geddes.com
amayo@ashby-geddes.com

I further certify that on April 5, 2013, I caused to be served by electronic mail copies of the foregoing document upon the following counsel of record:

Paul J. Berman
Keith A. Teel
Uma N. Everett
Erica N. Andersen
COVINGTON & BURLING LLP
1201 Pennsylvania Ave., NW
Washington, D.C. 20004
(202) 662-6000
pberman@cov.com
kteel@cov.com
ueverett@cov.com
eandersen@cov.com

/s/ Travis S. Hunter
Travis S. Hunter (#5350)
hunter@rlf.com